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510(k) Summary or 510(k) Statement

JUL 2 2 2011

K111152

510 (k) Summary

This summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92.

Submitter:

Villa Sistemi Medicali S.p.A.
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20090 Buccinasco (MI)
ITALY
Registration # 8021091

Contact Person:

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QA Manager
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Designated Agent:

Roy Torzullo
Del Global Technologies
100 Pine Aire Drive
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Registration # 9027610

Date Prepared:

April 18, 2011

Trade Name:

Rotograph EVO 3D

Common Name:

Dental panoramic/tomography and cephalometric x-ray system

Classification Name:

872.1800 System, x-ray, extraoral source, digital

Class:

II

Product Code:

MUH

Predicate Devices:

The Rotograph EVO 3D is compared with the following predicate devices:

- Villa Sistemi Medicali Rotograph EVO D (K090749),
- Planmeca ProMax 3D (K060328).

Product Description:

Rotograph EVO 3D is a panoramic x-ray system utilizing digital imaging. It can be equipped with a cephalostat. The device can be equipped with accessories to fulfil different diagnostic needs. The images are acquired by a flat panel detector and are displayed on a monitor, and image processing, manipulation, archiving, communication and 3D reconstruction (starting from cross-sectional images taken using CBVT (Cone Beam Volumetric Tomography) technique)) are performed via a computer.

Indication for Use:

Rotograph EVO 3D, panoramic x-ray imaging system with cephalostat, is an extraoral source x-ray system, which is intended for dental radiographic examination of the teeth, jaw, and oral structures, specifically for panoramic examinations and implantology and for TMJ studies and cephalometry, and it has the capability, using the CBVT technique, to generate dento-maxillofacial 3D images. The device uses cone shaped x-ray beam projected on to a flat panel detector, and the examined volume image is reconstructed to be viewed in 3D viewing stations.

2D Images are obtained using the standard narrow beam technique. The device is to be operated and used by dentists, radiologists and other legally qualified health care professionals.

Rationale for Substantial Equivalence:

Rotograph EVO 3D has the same indication for use as the predicate devices. It shares the same technological characteristics as the predicate devices. Minor technological differences do not raise any new questions regarding safety or effectiveness of the devices.

Safety and Effectiveness Information:

The device labeling contains operating instructions for safe and effective use of Rotograph EVO 3D. The software development for this device follows documented processes for software design, verification and validation testing. Final device validation and risk assessment has been conducted, to identify potential design hazards that could cause an error or injury based on the use of this device. Appropriate steps have been taken to control all identified risks. The device has been tested for compliance to IEC 60601-1 Medical Electrical Equipment Part 1: General Requirements for Safety. and its derivatives

Conclusion:

Rotograph EVO 3D performs the same functions in the same environment as the predicate devices. It shares the same technology as the predicate devices. It is based on well known technology. It is as safe and effective as the predicate devices. We believe it does not introduce any new potential safety risks and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Paolo Casagrande Santin
Quality Assurance Manager
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via delle Azalee 3
Buccinasco, MI, 20090
ITALY

JUL 22 2011

Re: K111152
Trade/Device Name: Rotograph EVO 3D
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: April 18, 2011
Received: April 25, 2011

Dear Mr. Casagrande Santin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

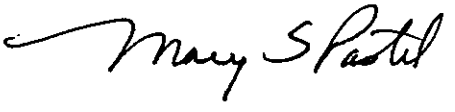
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,



Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111152

Device Name: Rotograph EVO 3D

Indications for Use:

Rotograph EVO 3D, panoramic x-ray imaging system with cephalostat, is an extraoral source x-ray system, which is intended for dental radiographic examination of the teeth, jaw, and oral structures, specially for panoramic examinations and implantology and for TMJ studies and cephalometry, and it has the capability, using the CBVT technique, to generate dento maxillofacial 3D images. The device uses cone shaped x-ray beam projected on to a flat panel detector, and the examined volume image is reconstructed to be viewed in 3D viewing stations. 2D images are obtained using the standard narrow beam technique. The device is to be operated and used by dentists, radiologists and other legally qualified healthcare professionals.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Patel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K111152